LA-UR 99-2459

Energy & Process Engineering

QUALITY ASSURANCE PLAN
FOR THE
ENERGY AND PROCESS ENGINEERING GROUP
(ESA-EPE)
OF THE
ENGINEERING SCIENCE and APPLICATION DIVISION

Los Alamos National Laboratory
University of California

Revision 2
June 2000

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Revision 2: Implementation Date: June 5, 2000
Revision 1: Implementation Date: October 27, 1998
Revision 0: Implementation Date: May 28, 1997

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ESA-EPE QUALITY ASSURANCE PLAN

Introduction

This document outlines a Quality Assurance plan for work performed by the Energy and Process Engineering Group of the Engineering Sciences and Applications Division (ESA-EPE) of Los Alamos National Laboratory (LANL).

ESA-EPE conducts both basic and applied research in the areas of electrochemical engineering, process control, robotics and automation, heat pipes, cryogenic engineering, chemical kinetics/transport, and general process system and component design.

ESA-EPE represents a group of diverse engineering talent that provides a wide range of expertise in a variety of program areas. Group personnel work on programs ranging from basic engineering research to development of complex computational fluid dynamics models; from simple modern control systems to advanced controls using fuzzy logic and neural networks; from cryogenic system applications to high temperature systems; and from single step robotics operations to fully automated processes, as well as in other areas that are vital to the Laboratory and the Nation.

The group personnel are trained in a variety of engineering disciplines including mechanical, chemical, electrical, engineering physics, metallurgical, and aerospace. In addition, the group has chemistry and physics expertise. A core of mechanical, electro-mechanical, and electrical technicians provide support to the group's experimental programs. Supplementing the group's technical capabilities are a number of technical contractors, postdoctoral fellows, and graduate research students.

Purpose

This QA plan supplements the "ESA Quality Policy" (http://www.esa.lanl.gov/lanl-only/esa-quality/esa_quality.pdf) to address programs and activities specific to ESA-EPE. The purpose of this QAP is to establish a quality program within ESA-EPE that will achieve the levels of quality and operational performance to satisfy the requirements of:

- DOE Order 5700.6c, *"Quality Assurance,"*
- Title 10 of the Code of Federal Regulations Part 830.120, *"Quality Assurance,"* for any work performed in a nuclear facility, as defined by the DOE.

Scope

The ESA-EPE Quality Program described in this document will improve quality while decreasing cost by efficiently identifying and streamlining operations. The responsibility for quality in ESA-EPE starts with the group leader and permeates the entire organization. The ESA-EPE group leader has determined the scope and rigor of the QA program outlined in the balance of this document. Each individual in the organization is responsible for the success of this plan. Group management, team leaders, and project leaders are responsible for creating an atmosphere in which common sense quality flourishes. Every group member assumes a role and share of the responsibility for quality.

Objective

The requirements established in this QA plan will be implemented by ESA-EPE personnel through written plans, procedures, and/or instructions. In accordance with the ESA Division QMP, a "graded approach" to QA will be taken to assure that quality is applied at a level commensurate with the amount of detail required for activities based on (1) risk associated with the task; (2) hazards to the public, workforce, and environment (in descending order); and (3) the consequences of failure including customer satisfaction and contractual agreements. With this in mind, the objectives of the ESA-EPE quality assurance program are:

- To achieve a level of quality necessary for accomplishment of program objectives commensurate with: the level of risk associated with the task; responsibility for health and safety; protection of the environment; and dependability and continuity of operations as required by the program.
- To assure that all activities affecting projects and facilities are accomplished in accordance with approved criteria, specifications, drawings and other contract requirements.
- To prevent costly and time consuming delays, rework, repairs, and modifications due to rejections or failures.
- To assure that appropriate quality assurance requirements, codes, and standards are implemented by ESA-EPE personnel.

Limitation

This plan is to be used to guide the ESA-EPE operations to the extent that it does not conflict with or interfere with project specific QA plans already in effect. In the event that ESA-EPE personnel work on a project or perform work for another organization, either internal to or external to the Laboratory, and said project or organization has a QA plan in place, that QA plan will take precedence over this QA plan for that project and ESA-EPE personnel will abide by the procedure established by that project QAP.

The balance of this document is laid out in sections that correspond to the ten criteria of DOE Order 5700.6c, "Quality Assurance". It has been determined that all ten criteria of the DOE order apply to ESA-EPE's work. Therefore, each section is addressed.

Note: Throughout this document, the term "principal investigator" is used. The term as used here is viewed from the perspective of the group, and is defined as the ESA-EPE person who has the lead role within the group for a given project or piece of work and who has the primary responsibility for completing that work*. Each project within the group, whether it is a one person effort or a multiple person effort, will have a person assigned to lead the effort. It falls to the principal investigator (as herein defined) of each project within the group to be the resident "expert" for that project and to be knowledgeable enough of the project requirements to determine the level of QA that should be applied. It is also the responsibility of that individual to apply the principles of this plan to the project as required.

* When viewed from a project perspective, this same person may or may not have a lead role, depending on the project.

Criterion 1 - PROGRAM

"Organizations shall develop, implement, and maintain a written Quality Assurance Program. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work. The QAP shall describe the management system, including planning, scheduling, and cost control considerations."

Organization

The organizational structure of ESA-EPE is documented at: http://ext.lanl.gov/orgs/esa/epe/epe_org.pdf . The organization chart shows the structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work.

The highest level of management within ESA-EPE shall be involved in quality program activities. This should include periodic review of the program established, and resolution of significant problems. This obviously cannot be done without data. See Section 3-Quality Improvement for a discussion of how this data will be collected.

QA Responsibility

The ESA-EPE Deputy Group Leader will have primary responsibility for implementing the QA Program, and for providing oversight for the necessary day-to-day QA activities. All ESA-EPE employees have the responsibility of following the procedures of the QA program.

Responsibilities and Authorities

The responsibilities and authorities of ESA-EPE line management, i.e. the group leader, deputy group leader, team leaders and project leaders can be found at:
http://int.lanl.gov:80/projects/pd/more/pd-roles.pdf .
Safety related roles and responsibilities can be found in Section 3.0 of LAUR-98-2837
(http://www.lanl.gov/orgs/ism/pdfs/desc_doc.pdf).
In addition, line management will be responsible for ensuring that an effective quality program is established and maintained, and for verifying that activities affecting quality have been correctly performed. Line management will:

- identify quality-related problems;
- initiate or provide solutions to quality-related problems; and
- verify implementation of solutions.

Although ESA-EPE line management is ultimately responsible for the achievement of quality, each individual of ESA-EPE is responsible for the quality of his/her work.

Stop Work Actions

Quality related Stop Work actions may be initiated by the ESA-EPE group leader, deputy group leader, a team leader, or a project leader if required in response to serious quality problems. Stop Work actions initiated for quality reasons should not be confused with safety related Stop Work actions since any LANL employee may initiate a safety related Stop Work action in accordance with LANL LIR 401-10-01.0, "Stop Work and Restart" (http://labreq.lanl.gov/pdfs/ops/lir/LIR4011001.pdf) when hazardous, potentially dangerous, or unsafe conditions exist.

Intentional distinction is made between *quality* and *safety* Stop Work actions because restart of activities is different in each case. Quality Stop Work actions shall be documented as non-conformances and resolved and restarted as required by applicable procedures. Safety Stop Work actions will be resolved and restarted in accordance with the aforementioned LANL LIR.

Criterion 2 - PERSONNEL TRAINING AND QUALIFICATION

"Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained."

Training

ESA-EPE personnel performing work shall be capable of performing their assigned tasks. The qualification requirements shall be established and documented for specific job categories. Training of ESA-EPE personnel will include both education in principles and enhancement of skills and practices. Training will ensure that the ESA-EPE employee understands the processes and tools that he/she uses. Personnel performing work that requires special skills or abilities will be qualified prior to performing work. The qualification process will be documented.

Training and indoctrination programs will, at a minimum, involve familiarization of personnel with technical objectives of the project including the codes and standards to be applied, and engineering and QA practices to be employed. Training instruction shall address potential consequences of improper work and focus attention on "doing the job right the first time."

Training Documentation

Personnel training will be documented in accordance with the LIR 300.00.04.0 – "Laboratory Training: A Graded And Systematic Approach To A Qualified Workforce" (http://labreq.lanl.gov/pdfs/ops/lir/LIR3000004.pdf). Training records will be kept in the ESA Division Training Office. Training received through the Los Alamos National Laboratory (LANL) Training and Development Center (TDC) will be recorded electronically and records can be retrieved on-line. Specialty training, including on-the-job training, off-site training, and other forms of training not accomplished through the LANL TDC shall be documented and supplied to the ESA Training Office in accordance with ESA Training Office procedures.

Criterion 3 - QUALITY IMPROVEMENT

"The organization shall establish and implement processes to detect and prevent quality problems and to ensure quality improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected. Correction shall include identifying the causes of problems and preventing recurrence. Item reliability, process implementation. and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement."

The ESA-EPE Group Office will establish and implement a process to promote continuous improvement by promoting a culture in which each employee of ESA-EPE believes and feels that he/she can make a difference in ESA-EPE's product and service. ESA-EPE management will ensure that proper focus is continuously given to a quality improvement process.

All ESA-EPE personnel are empowered to establish and implement processes to detect and prevent quality problems and to ensure continuous quality improvement. Employees are to be encouraged to seek new and innovative ways to ensure that product and service quality are the best that they can be.

The primary purpose of the quality improvement process is to prevent problems from occurring, however, they will still occur; therefore, provisions must be made to identify, resolve and prevent their recurrence. ESA-EPE management will foster a "no fault" attitude to encourage employees to identify problems that may compromise facility safety and reliability.

Nonconforming items or processes shall be systematically identified, controlled, and corrected. Corrective action shall include the identification of root cause and specific actions to prevent recurrence.

One of the biggest issues is the lack of documented data in the Group. Team and project leaders should start making notes (which can even be hand-written) on specific instances of quality improvements related to their products. This information can be collected from their people on a low profile basis, even without saying that it is QIP. Quality improvements can be driven by customers detecting problems with the product, or group personnel just wanting a product to be more cost

effective or safer. The group can discuss these (perhaps at Team Leader meetings) on a regular basis and the data collected and placed in a "QIP" folder. Group management should make a self-assessment based on the data and recommend an action plan. This can also be the basis for the "awards" program in the Division.

Corrective action procedures will be written to address remedial corrective actions, i.e., procedures for reviewing what, if any, impact a non-conformance might have on other parts of the system or project. The procedure will address not only how to prevent recurrence of the non-conformance, but how the ripple effect of the non-conformance to other parts, if any, will be mitigated.

The corrective action procedures will address what follow-on actions are required to ensure that corrections or improvements are actually implemented.

The “Quality Checklist for Improved or Reengineered Processes” found at http://peak.lanl.gov:1500/pdfs/qp/qualityc.pdf or a similar process will be followed to ensure quality improvement of process and product.

Non-conformances and corrective actions will be appropriately documented per the procedures developed in the next section of this plan, DOCUMENTS AND RECORDS.

Criterion 4 - DOCUMENTS AND RECORDS

"Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

Documents

Guidance for ESA-EPE personnel for preparing, reviewing, approving, issuing, using, and revising documents that establish policies, prescribe work, specify requirements, or establish design can be found at the LANL website http://int.lanl.gov/cic10/pdfs/prd115010.pdf . Documents that fall in this category include, but are not limited to, drawings, specifications, calculations, procedures, computer codes, purchase orders, vendor-supplied documentation, work instructions, operator aids, and data sheets.

Superseded and/or canceled documents will be destroyed or controlled to ensure that only correct documents are in use by ESA-EPE personnel.

Revisions to controlled documents will be reviewed and approved by the individuals that originally reviewed and approved the document, or an alternative individual(s) may be designated by the ESA-EPE Group Leader, based on the individual's technical competence and capabilities. A method for distributing revised controlled documents will also be identified.

Controlled document masters will be maintained in the ESA-EPE Group Office. The ESA-EPE Group Office Administrator or his/her designee will be responsible for maintaining the records. A unique document numbering system will be established to prevent confusion with the numbering system used for memos in the group office.

Records

Guidance for ESA-EPE personnel to follow to ensure that records are specified, prepared, reviewed, approved, and maintained properly can be found at: http://int.lanl.gov/cic10/pdfs/prd115020.pdf . ESA-EPE will verify that required records are prepared as work is performed in order to provide documentary evidence of the quality of the items and activities. It will be the responsibility of the individual

ESA-EPE principal investigators to ensure that records are retained, protected and retrievable as instructed by the procedure. The level of protection required and how the records will be protected will be determined by the project or by the EPE principle investigator.

Records that require special processing and control, such as computer codes and software, and information stored on high density media or optical disks, shall also have a system developed to maintain and control these records to ensure they are readily retrievable and usable.

QA records will be submitted in such a manner that legibly and completely record the required data. Records will be considered valid only if stamped or signed, and dated by authorized personnel.

A procedure will be developed to address how records will be corrected or modified once they are entered into the records management system.

Criterion 5 - WORK PROCESSES

"Work shall be performed to established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained."

Work

ESA-EPE personnel performing work are responsible for the quality of their work. These personnel must be knowledgeable of requirements for work they perform and the capability of the tools and processes they use. ESA-EPE team leaders and project leaders must ensure that personnel working under their supervision are provided the necessary training, resources, and administrative controls and support to accomplish assigned tasks. To achieve this, team leaders and project leaders will routinely review work and related information to ensure that the desired quality is being achieved and to identify areas needing improvement. The process of how the work will be reviewed and how the review is to be documented shall be documented

ESA-EPE work will be planned, authorized, and accomplished under controlled conditions. This is accomplished by using technical standards, instructions, procedures, or other appropriate means of a detail commensurate with the complexity and risk of the work.

Work related procedures, instructions, and other forms of direction will be developed, verified, validated, and approved by technically competent personnel within ESA-EPE group. As required, these procedures will be reviewed and verified independently by someone other than the author of the procedure.

Benchmarks for Quality Work

Generally, only high quality (unclassified) work can be published in the open literature. In the effort to maintain the highest quality of engineering R &D, the Group will encourage and maintain a list of refereed publications, conference papers, R&D 100 awards, etc. The Group will encourage its members to collaborate with universities and institutions of higher learning to assure a high level of technical competence. As a way of measuring our technical capabilities with other R&D institutions, the Group will bid for competitive contracts,

especially in the DoD and NASA arenas. Above all other measures, customer feedback on quality of work performed will be sought.

Identification and Control of Items

A documented procedure, process, or instruction will be developed as required that will provide a means to identify and control materials, parts, and components, including partially fabricated assemblies, in order to prevent the use of incorrect or defective items during project activities.

ESA-EPE principle investigators shall be responsible to verify that only specified, correct, and accepted items are used and installed during project activities.

ESA-EPE principle investigators shall be responsible to verify that materials, parts, and components are properly related to applicable controlled documents such as drawings or specifications.

Handling and Storage

A procedure or process shall be developed and implemented, as required, to control the handling, storage, shipping, cleaning, and preservation of items to prevent damage, loss or deterioration. ESA-EPE project personnel will verify that adequate procedures are used for the proper identification, control, and traceability of items. Items will be cleaned and stored in accordance with manufacturer's recommendations and/or project specific requirements. Withdrawal of items from storage will be appropriately documented.

Items transferred to or removed from storage will be handled in a manner to preclude damage. The traceability of these items will be maintained as required. Critical, heavy, or major items will be handled in accordance with approved procedures, as required.

Calibration and Maintenance of Monitoring and Data Collection Equipment

A documented procedure, process, or instruction will be developed and implemented by ESA-EPE to control the calibration, maintenance, and use of measuring and test equipment used by its personnel for monitoring and data collection activities.

Any of the test equipment used by ESA-EPE personnel for monitoring and data collection must be of the accuracy and type suitable for the intended use. The appropriate types of equipment will be specified. A system will be established that will provide a means of identifying these specific pieces of test and monitoring equipment by name, serial number, and records or certifications proving the calibration status. These calibration certifications will be traceable to national standards, where possible. Calibrations will be documented. Calibration procedures will address how the calibration will be documented.

Software

A documented procedure will be developed to address work processes involving software development and/or off-the-shelf commercial software implementation. The accuracy of software will be verified and

documented with hand calculations and/or other suitable comparisons to validate the software.

Environment, Safety, and Health

The quality of work processes in ESA-EPE includes attention to safety, environment, and personnel health. All work processes will be evaluated for ES&H impacts before they are implemented. The Laboratory Integrated Safety Management Plan will be used for guidance.

Criterion 6 - DESIGN

"Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design."

This guideline provides procedures, processes, or instructions for the control and management of design activities. A graded approach is used so appropriate standards are applied to the design activity and documented to the appropriate level. Sound engineering/scientific principles and drawing standards (See ESA Division Drafting and Design Standards and Guidelines) will be utilized. ESA-EPE is primarily an experimental engineering organization that designs and builds experiments for its external customers and experimenters within the Group. It therefore has the responsibility of assuring that its experimental hardware is safe, reliable and cost-effective.

Design management levels

Design basis, performance requirements, regulatory requirements, codes, and standards are identified, documented, and their selection reviewed and approved by the appropriate team leader and/or project leader, or negotiated with the customer. These factors determine to what level the design activity must be managed. A project's design level must be declared in the Statement of Work as either Conceptual, Developmental, or Product level designs. This information must be communicated to all project personnel and other contacts.

Conceptual Designs are often used by engineers and designers for scoping studies in proposals, and for designing small laboratory experiments. They very often use drawings based on sketches or simple CAD software. The Group uses a SK-numbering system for all of its sketches. They are generally used for fabricating one-of-a-kind experimental pieces. The criterion used in declaring this design level is that any defect in the product results in a low consequence impact to the project. This implies that the product's design and fabrication costs are low, and the consequence of the defect in the product is limited to the product itself, and does not result in far-reaching consequences.

However, it is required that independent checkers verify the work of the designer/engineer to assure high probability of workability of the design. These designs are generally for **internal use only.**

Developmental Designs for a Research and Development System are more complex designs where parts need to fit together into an assembly that can often become complex and expensive. The consequences of an unworkable design may affect the entire experimental system, so that the cost of designing and fabricating the system again would have significant impact on the project in time and cost. Developmental Designs again, are generally one-of-a-kind designs. These designs are declared **developmental** when a **conceptual design** shows high probability of workability and is funded. These developmental designs are almost always subject to customer review. They require at least two independent reviewers and a classification review. A change control process is also required. There continues to be significant interaction between the designer and the experimental personnel, who are responsible for the assembly and operation of the fabricated system.

A significant fraction of developmental design standards are specified by the customer. Developmental drawings for facility applications (TA-55 and Rocky Flats Plant) are generally purchased from external sources. The following is an example of NMT-specified standards and QA specifications and describes the interactive process of validation and verification between customer and supplier.

TA-55 DMO Furnace: The design task begins with work package agreements specifying standards and specifications. **A conceptual design** that begins with an engineering scoping study will almost always begin with hand drawn or CAD sketches. As-built drawings generated either within the group or contracted externally are expected to follow industry standards (for details, refer to ESA Division Drafting and Design Standards and Guidelines). An internal review committee consisting of 7-15 members is formed to review the conceptual and formal designs. This process is iterated until all errors are corrected. The process is now handed over to NMT Division for a Hazard Analysis Review. After safety issues have been addressed the NMT QA specialist (using standards set by NMT NQA-1) reviews the design document and institutes the change control process, which includes the TA-55 Design Change Process. Once these changes have been approved, the design is ready for fabrication. A"cold" test program outside of TA-55 is the first verification test of the design. NMT conducts a Cold Acceptance Review at the conclusion of this program. After changes to correct deficiencies have been made, a "Hot" Test and License to Operate the system at TA-55 is issued.

Product Designs: The Group very rarely generates a product design that is used to manufacture parts or assemblies in significant numbers. The last design generated as a product design was the nuclear material

storage containers that were part of the Advanced Recovery and Integrated Extraction System (ARIES).

Design verification (Design Review)

Design verification will be performed and documented by qualified individual(s) or group(s) other than those who performed the original design. These individuals or groups may be from within ESA-EPE. The extent of design verification will be based on the complexity, risk, and uniqueness of the design as determined by the EPE principle investigator.

Verification methods should include but not be limited to, design reviews, alternate calculations, and qualification testing. The appropriate verification method will be determined by the EPE principle investigator and documented prior to the verification process. Design verification will be completed before the design output is released for use by others, or to support other work. If the timing of this verification cannot be achieved, the unverified portion of the design will be identified and controlled. In all cases, design verification shall be completed before relying on the item to perform its function and before installation becomes irreversible.

Changes to final design

Changes to the design that include field changes, modifications, and nonconforming items designated "use as is" or "repair" shall be justified by the responsible ESA-EPE principle investigator. Changes will be approved by the original design organization that reviewed and approved the original design, or a technically qualified designate. Reviews and approvals of design changes will be documented.

Design interfaces

Design interfaces with other design organizations and customers participating in a particular design will be identified and controlled. Design efforts will be coordinated among and within the participating design organizations and the customers. Interface controls will include assignment of responsibilities and establishment of procedures among the participating design organization.

Design Records

Records will be maintained to provide documented evidence that the design was properly reviewed, approved, and accomplished. These records will include final design output, any revisions to the design, design steps (i.e. calculations, analyses, and computer programs), and any other sources of input that support the final design.

Peer or technical reviews of the design that are to be conducted by a project participant will be conducted in accordance with a written procedure. The reviews and documentation of the qualifications of personnel performing such reviews will be required.

Technical Review

A technical review is a formally documented review of technical material performed by individuals independent of those responsible for the work, but who may be members of ESA-EPE or the organization within which the work was done. A technical reviewer has technical expertise

at least equal to that of the individuals who prepared the material under review. A technical review is performed for material that is within the current state-of-the-art; the review is an objective evaluation of the technical content based on well-known and generally accepted standards.

Peer Review

A peer review is a formally documented review of technical material performed by individuals who are independent from the organization that performed the work and have technical expertise at least equivalent to that of the performing individuals. A peer review may be conducted when underlying technical work is at the forefront of the state-of-the-art technology or when technical conclusions are based, at least partially, on subjective judgments or application of existing theories to new ideas.

Criterion 7 - PROCUREMENT

"The organization shall ensure that procured items and services meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. The organization shall verify that approved suppliers can continue to provide acceptable items and services."

Procurement

A documented procedure, process, or instruction will be developed as required to document and control the procurement of items and services. A graded approach will be taken in procurement activities and the procedure will delineate the procurements that require strict QA processing. The procedure will also delineate the interface between the ESA-EPE requester and the BUS division buyer. The roles and responsibilities of each organization with regards to the procurement cycle will be defined.

If project requirements dictate application of quality procedures to procurement, the cognizant ESA-EPE principle investigator will determine from specifications, drawings, and procurement documents the technical requirements and applicable codes, standards and necessary QA activities associated with that procurement.

The ESA-EPE principle investigator will verify that only specified, correct, and accepted items and services will be used, and that materials, parts, and components are properly related to applicable control documents, such as drawings or specifications.

Methods of verification will be appropriate to the requirements of the specific procured item or service. This will include one or more of the following:

- source evaluation and selection;
- receipt inspection;
- objective evidence or quality; and
- source surveillance and audit.

Source Evaluation and Selection

Selection of suppliers will be based on the supplier's technical ability, financial responsibility, and QA program to provide items or services in accordance with applicable requirements defined by ESA-EPE principle investigators. Qualified suppliers and, as necessary, sub-tier suppliers will be monitored periodically by ESA-EPE personnel to ensure that acceptable items and services continue to be supplied.

Source Surveillance will be performed as required by ESA-EPE personnel to ensure that supplier's services, and manufacturing processes meet all required specifications and that identification markings correspond at all stages from initial receipt of an order through fabrication and shipment. Verification will also be made that corresponding documentation meets specified requirements.

Receipt Inspection

Qualified personnel of ESA-EPE will perform and document receiving inspections as required to verify conformance to procurement requirements. Provisions will be made for holding items or services pending receipt of specified documentation. Nonconforming items will be segregated and marked as nonconforming, until satisfactory corrective action has taken place.

Objective Evidence of Quality

Objective evidence of quality will be required from suppliers in accordance with item or service specifications listed in procurement documents. Examples of such evidence includes:

- certificates of conformance to required specifications;
- certificates of compliance to required specifications;
- test reports with traceability required (serial Number, Lot Number, or some other unique number);
- inspection reports;
- chemical properties certification; and
- physical properties certification.

Source Surveillance and Audit

Source surveillances and audits will be conducted when contractually required or when the assembled condition of the item or other reasons preclude adequate receipt inspection of important characteristics. These surveillances and/or audits will be performed in accordance with written procedures generated for the purpose by cognizant project/contract personnel.

If there are any cases that indicate that suppliers of items or services knowingly supplied substandard quality, this information will be

documented and will be forwarded through the ESA-EPE Group Office to the appropriate project and contract personnel, up to and including the DOE Office of Inspector General if necessary.

Criterion 8 - INSPECTION AND ACCEPTANCE TESTING

"Inspection and acceptance testing of specified items and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained."

Inspection

A documented procedure, process, or instruction will be developed and implemented as required that will provide guidance for specifying when and what type of inspections (source, in-process, final, receipt, maintenance, and in-service, for example) will be required. Results of inspections will be documented and retained to become a permanent record of the specific project. Inspections for acceptance will be performed by qualified persons other than those who performed or directly supervised the work being inspected. The necessary qualifications for an inspector to have in order to perform the inspection will be documented, as will the actual qualifications of the inspector.

Inspection procedures, processes, or instructions, checklists, or plan will contain at least the following:

- identification of item characteristics and process to be inspected;
- identification of individual(s), or organization who will perform the inspection activities;
- inspection techniques to be used;
- identification of any required hold points;
- acceptance criteria;
- requirement that a formal inspection record for each item on the checklist, or plan be developed;
- all inspection records will be approved by appropriate signature and dated;
- inspection records will be a part of the project file.

When acceptance criteria are not met, deficiencies will be resolved and re-inspection will be accomplished until acceptance is achieved.

Acceptance Testing

A documented procedure, process, or instruction will be developed and implemented as required that will demonstrate that items and processes will perform as intended. ESA-EPE will ensure that required and appropriate tests are identified performed and documented.

Testing will be conducted in accordance with test procedures that incorporate or reference the performance requirements included in the design specifications or other procurement documents. Test procedures will include provisions for at least the following requirements:

- use of calibrated equipment;
- technical and safety instructions;
- acceptance criteria;
- applicable hold points identified;
- completeness and accuracy of test data;
- appropriate test equipment;
- provisions for data collection and storage (test records);
- trained personnel; and
- suitable environmental conditions.

Appropriate sections of codes or standards may be used for acceptance requirements or test methods in lieu of specially written test procedures, with approval of the responsible ESA-EPE principle investigator.

Test results will be evaluated, verified, and documented to ensure that test requirements have been satisfied. As a minimum, test records will identify:

- item tested;
- date of test;
- tester or data recorder;
- results and acceptability
- authorized signature of approval; and
- action taken concerning any deviations noted.

Inspection, Test and Operating Status

A documented procedure, process, or instruction will be developed and implemented as necessary that will include administrative controls and status indicators to prevent bypassing of required inspections or tests and/or the operation of the item, process or system before acceptance is verified.

This process will preclude the inadvertent bypassing of required tests and inspections, and the inadvertent operation of nonconforming, non-tested, or non-inspected items or systems. Appropriate ESA-EPE principle investigators will verify that all project required tests and inspections have been satisfactorily performed.

The status of inspection and test activities will be identified, either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests have been performed.

Measuring and Test Equipment

A documented procedure, process, or instruction will be developed and implemented as necessary to establish requirements for a calibration system to ensure that Measuring and Test Equipment (MT&E) used to verify in-process or final acceptance inspection or test of an item or to control any process parameter which may influence the quality of an item characteristic, will be properly calibrated, maintained, accounted for and used. The required accuracy of MT&E to be use for each application will be specified.

Calibration intervals of MT&E will be specified on the basis of the device's required accuracy, intended use, frequency of use stability characteristics, and other conditions that may affect its performance. Some applications and types of MT&E, may need to be calibrated before and after each use. These applications will be identified as appropriate.

MT&E shall have calibration certifications traceable to national standards (where they exist), and the calibration standards shall have the required accuracy to ensure that the MT&E will be within the required tolerances. If MT&E is found to be out of calibration or out of tolerance, it should be tagged and segregated, and re calibrated before reuse. Any items or systems that were inspected or tested with a device that is found to be out of calibration or out of tolerance will be required to have their acceptability determined. Re-inspection or retesting of these items or systems may be required.

Criterion 9 - MANAGEMENT ASSESSMENT

"Management at all levels shall periodically assess the integrated quality assurance program and its performance. Problems that hinder the organization from achieving its objectives shall be identified and corrected."

ESA-EPE management will plan and perform periodic internal assessments of our organization's programs to develop a perspective on the overall adequacy and effectiveness of our management systems in achieving our stated QA objectives.

The management assessments that will be conducted are not intended to verify conformance to regulations, product standards, or established procedures. Rather, these management assessments are to evaluate customer and employee perceptions relative to the following issues:

- Mission and strategic objectives of ESA-EPE
- Employees' role in ESA-EPE
- Customers' expectations and degree to which the expectations are being met
- Opportunities for improving quality and cost effectiveness
- Recognizing and enhancing human resource capabilities

All management assessments will be documented and ESA-EPE management personnel will take prompt, but appropriate action in response to recommendations resulting from the management assessment process. Decisions and related actions resulting from the management assessment recommendations will be promptly followed up after implementation to provide evaluation of their effectiveness. This follow-up assessment will also be performed by ESA-EPE management personnel and will be documented.

Records of the management assessments, assessment responses, and follow-on actions will be maintained in the ESA-EPE Group Office as part of the group Quality Records and will be available for audit by independent assessment personnel if requested.

Criterion 10 - INDEPENDENT ASSESSMENT

"Planned and periodic independent assessments shall be conducted to measure item quality and process effectiveness and to promote improvement. The organization performing independent assessments shall have sufficient authority and freedom from the line organization to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed."

Planned and periodic independent assessments may be conducted by independent LANL groups and/or the DOE to measure item quality and process effectiveness and to promote improvement. Individuals and/or organizations who perform independent assessments shall have sufficient authority and freedom to carry out its responsibilities.

Personnel performing independent assessments shall act in a management advisory function and should be technically knowledgeable.

Assessment results will be tracked and resolved by appropriate ESA-EPE management personnel.

Responses to assessments shall include the following as applicable:

- action to correct the deficiency;
- cause identification (root cause);
- lessons learned;
- actions taken to prevent recurrence; and
- actions to be taken for improvement.